No. 15-7

IN THE

Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,

Petitioner,

v.

UNITED STATES AND COMMONWEALTH OF MASSACHUSETTS EX REL. JULIO ESCOBAR AND CARMEN CORREA,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, NATIONAL ASSOCIATION OF MANUFACTURERS, AMERICAN TORT REFORM ASSOCIATION AND NFIB SMALL BUSINESS LEGAL CENTER IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amici are organizations representing healthcare professionals, pharmacies, product manufacturers, and those concerned with the fairness of the civil justice system. *Amici* are concerned that the implied false certification theory, if adopted by this Court, will expose providers of products and services to the government to draconian penalties for minor instances of regulatory noncompliance and will contribute to the growth of opportunistic *qui tam* lawsuits under the False Claims Act.

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Through state and specialty medical societies and other physicians groups seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The AMA promotes the science and art of medicine and the betterment of public health. AMA members practice in every medical specialty in all fifty states. This Court and the federal Courts of Appeal have cited the AMA's publications and *amicus curiae* briefs in cases implicating a variety of healthcare issues.

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[1] Respondents have filed a blanket letter of consent to *amicus curiae* briefs with the Clerk of the Court. A letter from Petitioner consenting to the filing of this brief accompanies this brief. Per Rule 37.6, *Amici* state that no counsel for a party has authored this brief in whole or in part, and that no person or entity, other than the *Amici*, their members, or their counsel made a monetary contribution to the preparation or submission of the brief.

The National Association of Chain Drug Stores, Inc. ("NACDS") is a 501(c)(6) nonprofit trade association. Its mission includes advancing the interests and objectives of chain community pharmacies, including supporting their role as healthcare providers. NACDS membership consists of chain community pharmacy companies, including traditional drug stores, supermarkets, and mass merchants with pharmacies–from regional chains with four pharmacies to national companies. NACDS members operate more than 40,000 pharmacies in the United States and employ 179,000 pharmacists. NACDS members fill more than 2.9 billion prescriptions annually and aid patients in taking their medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 12 million men and women, contributes roughly $2.1 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for three-quarters of private-sector research and development. NAM's mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth.

The American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring

fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues.

The NFIB Small Business Legal Center, a nonprofit, public interest law firm established to protect the rights of America's small-business owners, is the legal arm of the National Federation of Independent Business ("NFIB"). NFIB is the nation's oldest and largest organization dedicated to representing interests of small-business owners in all fifty states. The approximately 325,000 members of NFIB own a wide variety of America's independent businesses from manufacturing firms to hardware stores.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court has warned against judicial rulings that would convert the False Claims Act ("FCA") from a targeted tool for fighting fraud against the government into an "all-purpose fraud statute." *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). This Court has further appreciated that expansive readings of the FCA can create "almost boundless" liability, *id.* at 669, and that, given this clear opportunity for the FCA to be misused, it is the courts' responsibility "to strike *a balance* between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Schindler Elevator Corp. v United States ex rel. Kirk*, 563 U.S. 401, 413 (2011) (emphasis in original) (quoting *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010)).

Despite these clear and repeated instructions, some courts, including the First Circuit here, have continued taking "a broad view of what may constitute a false or fraudulent" claim. *See* Slip Op. at 14 (internal citation omitted). In the case before this Court, the First Circuit improperly held that "each time" a company submits a bill to the government for services, it "implicitly communicate[s] that it ha[s] conformed" to every statutory, regulatory and contractual provision to which the transaction is subject. *See id.* at 19, n.14. The result of this ruling is that in order for a private person to bring an FCA claim, which is supposed to focus on acts of fraud against the government, and survive a motion to dismiss, he or she need only allege that the defendant violated some statute, regulation or contract. *Id.* at 14-15. The relator need not show the defendant fraudulently disregarded the provision, that it sought an ill-gotten government payment, or even that the government considered the violation serious enough to list it as a condition for payment. *Id.* at 15.

The Circuit Courts have dubbed these claims "implied false certifications." *See, e.g., United States v. Sanford-Brown*, 788 F.3d 696 (7th Cir. 2015) (holding the FCA does not support this theory). As the moniker suggests, a health care provider, manufacturer or other contractor is under no objective understanding that falling out of compliance with the statute, regulation or contract provision at issue would create exposure to the harsh penal structure of the FCA. The FCA violation is implied, with courts deciding after-the-fact whether it will choose to qualify the provision for FCA enforcement. In these cases, however, there is no actual false or fraudulent claim made to the government. *See United States ex rel.*

Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1218 (10th Cir. 2008) (acknowledging the implied false certification theory does not even look at the contractor's statements). The claims are mischaracterized as such in an effort to create opportunities to sue under the FCA.

There is a sharp distinction between statutory, regulatory or contractual violations and false or fraudulent claims. Implied certification claims find no support in the statute and do not resemble claims Congress had in mind when enacting or amending the FCA. They deprive contractors of their constitutional rights to have notice that they are engaging in conduct subject to heightened sanctions. Also, individuals do not normally have private rights of action to enforce statutes or regulations unless Congress expressly authorized them. As here, the relevant agency may have investigated the alleged violation and declined to intervene in the case. Further, to the extent a relator has an actual grievance with a contractor's product or service, the FCA is not the avenue for resolving such disputes. The FCA is not a product liability or wrongful death act; it is a fraud upon the government statute.

Amici respectfully urge the Court to end this FCA overreach. As lawyers have found creative ways over the past decade to turn minor disputes inevitable to contractual relationships into FCA claims, the number of *qui tam* suits has nearly doubled. *See* U.S. Dep't of Justice, Fraud Statistics, Nov. 23, 2015, *at* http://www.justice.gov/opa/file/796866/download [hereinafter "2015 DOJ Fraud Statistics"]. This increase in "opportunistic litigation," as this Court put it in *Schindler Elevator Corp.*, will only continue to

rise with the growth of federal regulations. 563 U.S. at 413. The Court should reverse the decision below to restore the FCA's moorings and ensure that its punitive liability is reserved for actually false or fraudulent claims against the government.

ARGUMENT

I. THE FCA HAS A LONG HISTORY OF BOTH FRAUD FIGHTING AND PRIVATE LITIGATION ABUSE

The FCA's enforcement regime has relied on encouraging people to sue companies that are defrauding the federal government by rewarding them handsomely if their lawsuits generate settlements or awards. The FCA uses mandatory large fines, including an automatic trebling of the amount in dispute, plus high per-incident fines and attorney fees, to punish those who commit fraud against the government and deter others from such egregious conduct. 31 U.S.C. § 3729(a). The private relator who brings the action keeps up to 30% of the award. *See* 31 U.S.C. § 3730(d). This incentive is competitive, in that only the first person to file a claim can become the relator for that matter, 31 U.S.C. § 3730(n)(5), and can generate life-changing wealth.

The pursuit of this FCA "bounty," as it has become colloquially known, has led to important recoveries for the government, and payouts to inside whistleblowers who uncovered actual and significant fraud upon the government in the form of goods or services not provided at all, or provided in woefully inadequate forms. *See generally* John T. Boese, Civil False Claims and Qui Tam Actions (4th ed. 2011). However, the opportunity for individuals to invoke

the threat of FCA's harsh penal structure to generate tremendous payouts has led to a long history of litigation abuse. *See id.* As this Court has observed, the FCA's penalties for punishing companies who commit fraudulent acts against the government are not appropriate in many of these situations. *See, e.g,. Schindler Elevator Corp.*, 563 U.S. at 413.

A. Cycles of Abuse and Course Corrections

Congress enacted the FCA, originally called "The Informer's Act," in 1863 to prevent unscrupulous contractors from fraudulently selling provisions to the Union Army during the Civil War. *See* Boese, *supra*, at 1-6; Larry D. Lahman, *Bad Mules: A Primer on the Federal False Claims Act*, 76 Okla. B.J. 901, 901 (2005) (providing examples of decrepit mules, faulty rifles, and rancid rations). Often, war profiteers acted with impunity because the scale and complexity of the war made identifying responsible parties and prosecuting frauds too onerous. The Act included several features of the modern statute: it applied to any fraud against the government, imposed penalties for each false claim, and authorized damages as a multiple of the government's loss. *See* Act of March 2, 1863, 12 Stat. 696-98 (1863).

When courts have interpreted the FCA too broadly, the statute has become fodder for abuse. *See* Victor E. Schwartz & Phil Goldberg, *Carrots and Sticks: Placing Rewards as Well as Punishment in Regulatory and Tort Law*, 51 Harv. J. on Leg. 315, 337-35 (2014). For example, when government involvement in the economy expanded through the New Deal and pre-World War II military buildup, this Court lowered the bar for the information needed for bringing a *qui tam* action. *See United States ex rel. Marcus v.*

Hess, 317 U.S. 537 (1943). The result was a dramatic increase in "parasitic" *qui tam* suits, as people found ways to game the system. *See United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 679-80 (recounting FCA's history). Some relators filed suits based on copying criminal indictments they played no role in helping to bring. *See id.* In 1943, Congress corrected this overreach by requiring relators to base claims on information the government did not possess. *See* False Claims Act, Pub. L. No. 78-213, 57 Stat. 608, 608-09 (1943).

Over the past 30 years, Congress has amended the FCA to address reports that fraud was pervasive in government contracts. For example, in the 1980s, contractors allegedly overcharged the military to the tune of $435 for a hammer, $640 for a toilet seat, and $7,600 for a coffee maker. *See* United Press Int'l, *Navy Paid $900 for Plane Ashtray*, Sun Sentinel, May 30, 1985. These reports led the Departments of Defense and Health and Human Services to triple their investigations into fraudulent claims. S. Rep. No. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5267. Congress responded by enacting the False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986).

Congress also reformed the FCA to address new types of fraud after the financial crisis in 2009 and 2010. *See* Fraud Enforcement and Recovery Act, Pub. L. No. 111–21, 123 Stat. 1617 (2009); Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A, 124 Stat. 1376, 2079 (2010) (amending 31 U.S.C. § 3730(h)); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. X, § 10104(j)(2), 124 Stat. 119, 901-02 (2010)

(amending 31 U.S.C. § 3730(e)). The FCA's purpose has remained recouping government losses suffered from *fraud*. S. Rep. No. 99-345, at 4 (1986) (describing the legislation as making the FCA "a more effective weapon against Government fraud").

B. Recent Reforms Did Not Authorize the New "Parasitic" Lawsuits

Lawyers specializing in bringing *qui tam* actions have claimed that these reforms justify their attempts to significantly broaden the reach of the FCA. Congressional amendments to the FCA over the past 30 years, though, do not authorize using the FCA for statutory, regulatory or contract enforcement, including under the false certification theory at bar.

Relevant to the litigation here, Congress changed the scienter requirement to no longer require the relator to prove the defendant had specific intent to defraud the government. The contractor could be subject to FCA liability if it had "actual knowledge" of a false or fraudulent statement. However, the contractor must act with "deliberate ignorance of the truth or falsity" or "in reckless disregard of the truth or falsity." 31 U.S.C. § 3729(b)(1)(B). This requirement for malevolence is often overlooked, particularly in the type of case at bar and in the pre-discovery phases of a case. Also, the false or fraudulent statement must be "material" to influencing the government's decision to pay a claim. S. Rep. No. 111-10, at 12 (2009).

Congress also created greater access to the FCA for potential relators and made it more lucrative for them. *See* 31 U.S.C. § 3730(e)(4)(B) (no longer requiring relators to be "insiders" with new information or first-hand knowledge of the alleged viola-

tion); 31 U.S.C. § 3729(a) (increasing per incident fines to their current level of $5,500 to $11,000 for each violation); 31 U.S.C. § 3730(d) (allowing the relator to keep up to 15% to 25% of the recovery when the government intervenes and up to 30% when the government declines to intervene). These are mandatory penalties, regardless of whether the government was actually injured or how minor the defendant's alleged misconduct. The result has been increased attempts to manipulate the FCA in the courts to support improper *qui tam* lawsuits.

Take a modest contract in which a manufacturer sells items to the government at $10 apiece. The government, which is billed individually for each item, purchases 1,000 of them for a total of $10,000. The government is satisfied with the purchase, but someone discovers the manufacturer was out of compliance with an applicable environmental or workplace regulation. He or she files an FCA claim saying every product was sold under the false premise of compliance with those regulations, threatening $30,000 in treble damages, aggregate civil penalties of up to *$11 million*, and attorneys' fees – a steep penalty for a $10,000 contract.

Many targets of these lawsuits, including *amici* physicians, pharmacies, and manufacturers, engage in such low-dollar, high-volume transactions in government-supported programs or with the government itself. Courts must be instructed to weed out such groundless claims at the motion to dismiss stage. Otherwise, targets of *qui tam* suits will have to settle meritless claims, as many do not have the resources to risk going to trial. *See AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740, 1752 (2011) (ap-

preciating that with "even a small chance of a devastating loss, defendants will be pressured into settling questionable claims"). A loss, regardless how remote on the merits, could financially ruin a defendant and impose the high reputational cost of being labeled a fraudster.

C. The Record Rise in *Qui Tam* Lawsuits

The result has been a wildly expanded *qui tam* bar seeking to leverage litigation inequities for settlements and awards. In many of the new *qui tam* lawsuits, relators have tried to turn what might otherwise be traditional disputes between the government and its contractors, including regulatory compliance and breach-of-contract claims, into *qui tam* actions – though Congress never intended them to be the subject of the FCA's harsh penalties. As this Court has appreciated, relators have no duty to exercise fair judgment. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("relators are less likely than is the Government to forgo an action arguably based on a mere technical noncompliance with reporting requirements that involved no harm to the public fisc.").

The statistics bear out this truth. In the mid-1980s, relators filed only a few dozen *qui tam* actions per year. *See* 2015 DOJ Fraud Statistics (reporting 30 *qui tam* actions in 1987). From the mid-1990s through 2009, an average of 300 to 400 *qui tam* suits were filed per year, with DOJ initiating about 150 claims per year. *See id.* Since 2009-2010, government filings have remained constant, but the number of *qui tam* filings has nearly doubled, spiking to 754 filings in 2013 and reaching 632 filings in 2015. *See id.*

The growth in claims is not limited to the pursuit of fraud, but the rebirth of "parasitic" lawsuits not envisioned or authorized by Congress. The government declines to participate in about 80% of relator-initiated claims,[2] which is viewed as a clear indicator that a given case lacks merit. *See, e.g., United States v. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 331 (5th Cir. 2011) (stating that the non-intervened claims "presumably lacked merit"); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 242 n.31 (1st Cir. 2004) ("[T]he government's decision not to intervene in the action also suggested that [relator's] pleadings of fraud were inadequate."). These claims, though, are still expensive and burdensome to defend, and can result in improper settlements, and even jury verdicts.

Much of this litigation has been trained on the health-care profession; Medicaid and Medicare reimbursements to physicians, hospitals, pharmacies, and pharmaceutical manufacturers create the government hook that can turn a traditional dispute into an FCA action. *See generally* Joan H. Krause, *Twenty-Five Years of Health Law Through the Lens of the Civil False Claims Act*, 19 Annals Health L. 13, 16 (2010) ("[T]o many critics the system appears ripe for abuse by self-interested relators with few, if any, real whistles to blow."). In 2015, two-thirds of federal *qui tam* actions targeted healthcare entities, with health

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[2] *See* U.S. Dep't of Justice, Press Release, Acting Assistant Attorney General Stuart F. Delery Speaks at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement, June 7, 2012, *at* http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html.

care-related claims doubling since 2008. *See* 2015 DOJ Fraud Statistics. Also, the Affordable Care Act, which increased government funding for health care, may expose even more transactions to FCA litigation abuse. *See* Beverly Cohen, *KABOOM! The Explosion of Qui Tam False Claims Under the Health Reform Law*, 116 Penn St. L. Rev. 77, 77 (2011). Building these costs into America's healthcare will hinder access to affordable and quality care.

About a quarter of *qui tam* actions target non-medical industries, including manufacturers. *See* 2015 DOJ Fraud Statistics. These contractors saw a record number of claims in 2014. *See id.* Defense contracting fraud, the original motivation behind the FCA and the 1986 amendments, accounted for only 5% of *qui tam* actions in 2015. *See id.*

II. FALSE CERTIFICATION CLAIMS: THE "MOST PROBLEMATIC" NEW SOURCE OF FCA LITIGATION ABUSE

False certification claims have been described as "the most problematic and troublesome FCA cases." *See* Boese, *supra*, at § 1.06. As here, there is no allegation the defendant defrauded the government or improperly sought payment, such as by inaccurately or incorrectly describing goods or services provided. Rather, the theory is that, for whatever reason, the contractor fell out of compliance with a regulation in providing the service or product, thereby turning an otherwise healthy transaction into a "false claim."

In some cases, contractors are required to state compliance with specific regulations in order to establish eligibility for a contract. For example, under Medicare, some health care providers were required

to certify that they were "familiar with the laws and regulations regarding the provisions of health care services and that the services identified in [the] cost report were provided in compliance with such laws and regulations." *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1041 (S.D. Tex. 1998). In other cases, as here, liability is premised solely on the implication that the contractor is supposed to be in compliance with the provisions to participate in the government program. *See Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (Fed. Cl. 1994) (establishing the implied false certification theory).

A. This Case Represents a Highly Tenuous Version of False Certification Claims

The case at bar is an outlier even among the recent spate of false certification claims. It is an implied certification claim based on alleged regulatory violations that were never included among the regulations that MassHealth prioritized as pre-conditions for payment. *See* 130 Mass. Code Regs. § 429.401 (listing the Code as a general requirement for mental health centers in the MassHealth program). By contrast, MassHealth has identified other regulations, for example 130 Mass. Code Regs. § 429.439, where the "[s]ervices provided . . . are reimburseable only if the program meets the standards described." The District Court dismissed the complaint, understanding that "not every regulatory violation gives rise to a potential FCA case." Pet. App. 37

To be clear, changes Congress made to the FCA in the past 30 years have not authorized the FCA to be used in these circumstances. As discussed above, the FCA still requires a contractor to knowingly submit a

false or fraudulent claim to the government material to the agency's decision to pay the claim. Thus under current law, the mental health facility here would have had to submit its invoices knowing they were false for the purpose of have the false or fraudulent claim paid. The knowledge requirement under the FCA is not mere knowledge of a regulatory violation.

Further, particularly with penal codes, a person must be able to anticipate which violations give rise to punitive liability. *See Allison Engine*, 553 U.S. at 672 (requiring courts to "ensure that a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct"). If an FCA claim could be filed every time a company submits a claim to the government when it is not in compliance with every applicable regulation, the FCA would become a statute without standards. In hindsight, particularly when someone has been injured, violations can appear to have greater import.

The Seventh Circuit addressed this concern by refusing to extend punitive FCA liability to cases in which a contractor's forward-looking assurances of compliance were not knowingly false at the time they were made. *See Sanford-Brown*, 788 F.3d at 709. "This distinction between fraud at the outset and breach of contract . . . is significant because a mere breach of contract does not give rise to liability under the False Claims Act." *Id.* at 710. As with the regulatory issue here, "[p]romises of future performance do not become 'false' due to subsequent noncompliance." *Id.*; *see also Lamers*, 168 F.3d at 1018-20 (also requiring finding that defendant never intended to comply with the contract).

Here, MassHealth investigated the allegations, took measures to address the violations, but did not seek to recover funds it had paid to Petitioner, much less seek to impose punitive financial liability. Also, neither the United States nor the Commonwealth of Massachusetts joined in the relators' claims. These decisions should be dispositive as to whether any regulatory violation was material to payment. It is easy to forget that *qui tam* actions, while initiated by relators, are actually brought on behalf of the federal government to protect the public fisc from fraud.

B. Circuits Find False Certification Claims are "Prone to Abuse"

False certification claims, particularly the type at issue here, have received mixed results in the courts of appeals, but many panels have cautioned that they "lack[] a discerning limiting principle." *Sanford-Brown*, 788 F.3d at 711. "[A] single regulatory violation would be a condition of *any and all* payments subsequently received by the facility inasmuch as the regulators *could* terminate the facility for practically any deficiency." *Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 712 (7th Cir 2014). Even courts allowing these claims have acknowledged they are "prone to abuse." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 270 (D.C. Cir. 2010) (cautioning that relators "seeking to take advantage of the FCA's generous remedial scheme" could try turning "the violation of minor contractual provisions into an FCA action").

"The False Claims Act was not designed for use as a blunt instrument to enforce compliance with all [ ] regulations." *Mikes v. Strauss*, 274 F.3d 687, 699 (2d Cir. 2001); *see also United States ex rel. Rosthold-*

er v. Omnicare, Inc., 745 F.3d 694, 702 (4th Cir. 2014) ("[T]he correction of regulatory problems is a worthy goal, but is 'not actionable under the FCA in the absence of *actual fraudulent conduct*."); *Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 269 (5th Cir. 2010) ("The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts."); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA."); *Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (It is not for "policing technical compliance with administrative regulations."). Otherwise, as this Court has cautioned, anyone could find "a federal contractor who is out of compliance, and potentially reap a windfall in a *qui tam* action." *Schindler Elevator Corp.*, 563 U.S. at 413.

III. THE FCA SHOULD REMAIN A STATUTE FOR FIGHTING FRAUD, NOT PRIVATE ENFORCEMENT OF REGULATIONS

Distinguishing between allegations of noncompliance and "false or fraudulent" claims for payment under the FCA is critical for three reasons. First, recognizing that noncompliance is not equivalent to fraud will focus *qui tam* actions on seeking recovery for government losses that actually resulted from false claims for payment. Second, this distinction will preserve agency discretion to address compliance issues through more appropriate means. Third, it will help ensure that the FCA's scheme of punitive liability does not over-penalize government contractors that while technically non-compliant, have actually performed a contracted service.

A. Imperfect Compliance is Not Equivalent to Fraud

Government contractors operate in a complex system that subjects them to thousands of regulations, in addition to statutory and contractual obligations. Flawless compliance with each provision may be practically impossible and is not required by the FCA. *United States ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 314 (3d Cir. 2011) (recognizing the FCA "does not require perfect adherence to regulations which are not prerequisite for payment").

The healthcare regulatory environment is especially complex, making it particularly inappropriate to use the hammer of FCA liability to punish noncompliance. As the Third Circuit has recognized, "anyone examining the Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them." *Wilkins*, 659 F.3d at 310; *see also* Richard Doan, *The False Claims Act and the Eroding Scienter in Healthcare Fraud Litigation*, 20 Annals Health L. 49, 74 (2011) ("The federal government cannot reasonably expect unsophisticated healthcare providers to navigate the maze of 15,000 Medicare regulations, 400 pages of Medicare laws, thousands of pages of CMS literature, 7,000 CPT codes, and 51 idiosyncratic state Medicaid programs."); Pamela H. Bucy, *Private Justice*, 76 S. Cal. L. Rev. 1, 66 n.350 (2002) ("[T]here are so many thousands of applicable rules and regulations applicable to government contractors that chaos would result if violation of any one or a few would render claims submitted by a contractor false.").

Further, manufacturers have identified compliance with the ever-growing body of federal regulations as, by far, their number one challenge. *See* W. Mark Crain & Nicole v. Crain, The Cost of Federal Regulation to the U.S. Economy, Manufacturing, and Small Business 8 (Nat'l Ass'n of Manuf. 2014), *at* http://www.nam.org/Data-and-Reports/Cost-of-Federal-Regulations/Federal-Regulation-Full-Study.pdf. According to this report, 88% of survey respondents identified federal government regulations as a challenge affecting business in the prior year or that will affect them in the future. *See id.*

Given the massive universe of regulations (as well as statutory and contractual obligations), the implied certification theory places a heavy burden on a contractor to verify continual compliance, exposing anyone that allegedly falls short of this challenge to extraordinary liability. Ironically, Congress enacted the FCA to provide an incentive for whistleblowers to report fraud because of the scale and complexity of identifying and prosecuting dishonest contractors. Now, contractors are operating under large and complex regulatory schemes. Should one falter, a *qui tam* plaintiff should not be able to misuse the FCA to bring a "gotcha" claim.[3]

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[3]*Qui tam* relators seize upon any issue that can be labeled a violation to bolster a weak FCA claim. *See, e.g., Chesborough v. VPA, P.C.*, 655 F.3d 461, 468-69 (6th Cir. 2011) (basing claim on industry *standards* and a theory of "worthless services" rather than an objective regulatory or statutory violation).

B. The Government Should Maintain Control Over Enforcing Its Regulations

Allowing FCA suits based on regulatory violations "would short-circuit the very remedial process the government has established to address non-compliance with those regulations." *Wilkins*, 659 F.3d at 310. Relators could punish violators even when the agency involved believes no action is warranted, has pursued an administrative remedy, or has secured changes in future conduct. *See United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1222 (10th Cir. 2008) ("It would be curious to read the FCA, a statute intended to protect the government's fiscal interests, to undermine the government's own regulatory procedures.").[4]

This Court has already determined that individuals do not have private rights of action to enforce statutes or regulations unless Congress expressly intended to create one. *See, e.g., Astra USA Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011) (finding Congress reserved enforcement of federal law governing pricing of drugs sold to certain healthcare facilities to U.S. Department of Health and Human Services and that private lawsuits would undermine HHS's efforts to administer the law); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 287-90 (2002) (finding plaintiff cannot use 42 U.S.C. § 1983 to effectively create a

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[4] Even if *the* government believes that a punitive sanction is unwarranted for noncompliance, under the FCA's statutory scheme, the government cannot exercise its enforcement discretion to stop a *qui tam* relator from pursuing the case and seeking treble damages and statutory penalties. *See Conner*, 543 F.3d at 1222. It can only decline to intervene, *see* 31 U.S.C. § 3730(c)(3).

private right of action under Family Educational Rights and Privacy Act's nondisclosure provisions, which are enforceable only by the Secretary of Education). Individuals should not be allowed to circumvent these rulings by repackaging their claims under the FCA, thereby creating backdoor, punitive private rights of action for potentially thousands of statutes and regulations and government contractors.

Interfering with agency management of its own contractors also compromises its ability to pursue the best results for the public. *See Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010). When an agency controls the enforcement of its own regulations, it can work with out-of-compliance providers to develop correction plans. *See Conner*, 543 F.3d at 1220-21. If the provider has not "substantially" complied, the agency, at its discretion, can terminate participation in the program. *Id.* (citing 42 U.S.C. § 1395cc(b)(2)). Such removal has been called the "ultimate sanction." *Conner*, 543 F.3d at 1220; *Mikes*, 274 F.3d at 702. Noncompliance does not give agencies the right to "wholesale recovery" of paid claims. *See United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 798-99 (8th Cir. 2011).

FCA claims, therefore, are worse than the "ultimate sanction." They retroactively revoke the contractor's participation in the program for the transactions at issue by requiring it to disgorge all proceeds and then adding punitive fines. Allowing private individuals to seek such penal measures would frustrate the government's "carefully crafted remedial process," and "be catastrophic" for individuals and companies that provide government services. *Conner*, 543 F.3d at 1220-21. As the courts of appeal have

explained, the FCA should not be such "a sweeping mechanism to promote regulatory compliance." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014).

Courts have also found that the FCA is not appropriate for enforcing breach of contract or product liability claims. *See Steury*, 625 F.3d at 270 (finding no FCA claim against medical device maker where pumps supplied to Veterans Administration hospitals allegedly failed to comply with standard warranty of merchantability in Federal Acquisition Regulations); *Mikes*, 274 F.3d at 700-702 (no FCA claim that physicians' performance of spirometry did not conform to professional guidelines); *United States ex rel. Yannacopoulos*, 652 F.3d 818, 824 (7th Cir. 2011) (distinguishing a "mere breach of contract" from a "breaching party [that] falsely claims to be in compliance with the contract to obtain payment").

Consider the example of *United States v. Science Applications Int'l Corp.*, 653 F. Supp.2d 87, 94 (D.D.C. 2009), *aff'd in part, vacated in part*, 626 F.3d 1257 (D.C. Cir. 2010). In this case, the D.C. Circuit allowed such a claim under an implied breach of contract theory. The jury awarded $5.9 million in damages and $577,500 in civil penalties under the FCA, but just $78 on the breach of contract claim. *See id.* The FCA's penalty structure, therefore, can be highly disproportionate to the alleged violation.

C. The FCA's Penalties Should be Reserved for Truly False or Fraudulent Claims

Finally, the Court should overturn the ruling below because indiscriminately imposing the hammer of the FCA—mandatory trebling of damages, per-incident statutory fines, and attorney fees—for non-

fraudulent compliance issues raises due process concerns that a contractor will not be on notice of when it is engaging in conduct that could give rise to these penalties. *See* 31 U.S.C. § 3729(a)(1).

This Court has recognized that the FCA's remedial scheme is "essentially punitive in nature." *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 785 (2000). For example, in 2015, three companies settled FCA claims in excess of $300 million each. *See* U.S. Dep't of Justice, Press Release, *Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015*, Dec. 3, 2015, *at* http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.

In *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, the Fourth Circuit allowed a $237 million FCA jury verdict to stand even though it threatened to put a nonprofit hospital serving a small rural community out of business. *See* 792 F.3d 364, 370, 387-90 (4th Cir. 2015) (rejecting arguments that the verdict violated the Due Process Clause or Excessive Fines Clause). The amount exceeded the provider's annual revenue and raised fears that the hospital would not be able to post the appeal bond. *See* Lisa Schencker, *$237 Million Tuomey Judgment Upheld by Federal Appeals Court, Modern Healthcare*, July 2, 2015, *at* http://www.modernhealthcare.com/article/20150702/NEWS/150709975.

The FCA claim alleged that the hospital's compensation arrangement with part-time physicians violated the Stark Law, 42 U.S.C. § 1395nn, which prohibits physicians from referring patients to healthcare facilities with which they had certain fi-

nancial relationships. The Stark law has proven highly challenging to interpret and apply, as the hospital received competing legal opinions as to whether its arrangements were Stark-compliant—including opinions finding it was in compliance from both a former Inspector General at the U.S. Department of Health and Human Services and prominent healthcare lawyer. Nevertheless, the judgment consisted of the full amount of each claim submitted for reimbursement, trebled, plus the statutory minimum ($5,500) for each submitted claim. *See id.* at 384.

A concurring judge emphasized the "troubling" nature of the case, in which "[a]n impenetrably complex set of laws and regulations [ ] will result in a likely death sentence for a community hospital in an already medically underserved area." *Id.* at 390 (Wynn, J., concurring). "It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act." *Id.* at 395.[5]

These concerns are especially salient in FCA litigation where the violation is merely implied through a statute, regulation, or contract. As this Court has recognized, it is essential to provide fair notice when

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[5] The Department of Justice ultimately settled the case for $72.4 million, allowing the hospital to continue operating under the condition that it is sold to a multi-hospital healthcare system. *See* U.S. Dep't of Justice, Press Release, *United States Resolves $237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians*, Oct. 16, 2015, *at* http://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital.

conduct can subject a person to a punitive sanction. *See BMW of N. Am. v. Gore*, 517 U.S. 559, 574 (1996) ("Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose."); *see also United States v. Aleff*, 772 F.3d 508, 512 (8th Cir. 2014) ("The FCA's treble damages in combination with the per-claim penalties are punitive for the purposes of the Excessive Fines Clause.").

Thus, whether a defendant is a healthcare provider, manufacturer or other contractor, this Court should find that merely certifying compliance with extensive statutory, regulatory, and contractual obligations does not give rise to an FCA claim if an entity falls out of compliance. This Court should reject such a groundbreaking and blanket theory of liability. *See Momence Meadows Nursing Ctr., Inc.*, 764 F.3d at 712 (calling a comparable theory "absurd").

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request that this Court reverse the judgment of the court of appeals.

Respectfully submitted,

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